

Exhibit C

Serous Ovarian Cancer Caused by Exposure to Asbestos and Fibrous Talc in Cosmetic Talc Powders—A Case Series

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Objective: Asbestos is a known cause of ovarian cancer. We report 10 cases of serous ovarian cancer among users of Johnson & Johnson (J&J) asbestos-containing “cosmetic” talc products. **Methods:** We conducted an asbestos exposure assessment during talc application and analyzed surgical tissues and talc containers for asbestos and talc. **Results:** Talc was found in all cases and tremolite and/or anthophyllite asbestos was found in 8/10 cases. The asbestos fibers found in the “cosmetic” talc containers matched those found in tissues. We estimated inhaled asbestos dose ranged from 0.38 to 5.18 fiber years. **Conclusion:** We provide evidence that the inhaled dose of asbestos/fibrous talc from “cosmetic” talc use causes ovarian cancer. The unique combination of the types of asbestiform minerals detected in cancerous tissue and “cosmetic” talc is a fingerprint for exposure to asbestos-containing talc.

Keywords: asbestos, baby powder, cosmetics, Johnson & Johnson, ovarian cancer, talc

Known amongst oncologists as a “silent killer,” ovarian cancer is the leading cause of death from all gynecologic cancers and the fifth leading cause of cancer-related deaths among women in the United States.¹ The American Cancer Society estimates that about 22,000 American women will be diagnosed and 13,850 will die of the disease in 2019.² In 2010, the agency determined that perineal talc powder use is possibly carcinogenic to humans (group 2b).³

Epidemiological studies have examined the relationship between perineal talc use and ovarian cancer. In a 1982 case-control study, Cramer et al⁴ first reported an association between genital talc use and ovarian cancer. At least 32 subsequent epidemiologic studies have examined the association between talc

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Institution and Ethics approval and informed consent: There was no requirement for ethics review or institutional review board approval because this research was not experimental and was originally conducted pursuant to a lawsuit. Informed consent was obtained from all living patients. For one deceased patient (Case No. 8), consent was obtained from the surviving spouse. For the remaining two deceased patients (Case No. 4 and Case No. 9), authors relied only on public information revealed during court proceedings.

Disclosure (Authors): T.T., J.S., K.C., M.Y. and T.B. work for Dr Egilman, who served as an expert witness in litigation at the request of people who were injured as the result of using talcum powders. Mr Tran, Ms Steffen, Ms Clancy, Ms Yimam, and Dr Bird were not compensated by law firms for work on this paper and the lawyers for the injured plaintiffs did not review this paper and had no input into the content of the paper.

Dr Egilman, Dr Rigler and Dr Longo report payments from lawyers related to the submitted work. All serve as expert witnesses in litigation at the request of people who were injured as the result of using talcum powders; plaintiffs' lawyers paid for the patient examinations taken by Dr Egilman as part of his expert witness work.

powder use and ovarian cancer.^{5–36} High-grade serous carcinoma (HGSC) is the most common form of ovarian cancer and the type of ovarian cancer that has been most consistently associated with perineal use of cosmetic talc products.^{6–8,10,12,14,15,24,27,29,32,33,36,37} Meta-analyses have consistently shown an increased risk of HGSC of about 1.3 for perineal talc use.^{18,38–40}

Asbestos exposure by inhalation occurs during cosmetic talc use.^{41,42} International Agency for Research on Cancer (IARC) concluded in 2009 that asbestos was a group 1 ovarian carcinogen.^{43,44} Dr Wyers' first reported a case of ovarian cancer in a woman with asbestosis in 1949.⁴⁵ Twenty-seven epidemiologic studies have since examined the relationship between asbestos exposure and ovarian cancer.^{46–72} Nine of these 27 studies report a statistically significant elevation in ovarian cancer risk.^{46–48,51,61,62,68,69,71} Epidemiologic findings have demonstrated consistency in different populations: studies of asbestos and ovarian cancer have shown a statistically-significant association among women in different countries with exposures to different types of asbestos fibers and in various occupational and environmental settings.^{46–48,51,61,62,68,69,71} Epidemiologic research also suggests a dose-response relationship for asbestos and ovarian cancer when comparing low-exposure and high-exposure subgroups.^{47,72} Camargo et al⁷³ performed a meta-analysis of 18 cohort studies of occupational asbestos exposure and reported a pooled standardized mortality ratio (SMR) for ovarian cancer of 1.77 (95% confidence interval [CI], 1.37–2.28).

Epidemiologic studies of talc and ovarian cancer have generally accepted representations by talc mining and manufacturing companies that consumer talc has been asbestos-free since 1976.^{6–8,10,12,14,15,24,25,27,29,32,36} However, studies show that

Dr Rigler and Dr Longo originally performed the tissue analysis for talc and asbestos as part of their expert witness work and were paid by plaintiffs' lawyers for their work. Dr Egilman has also served as an expert witness at the request of companies who have been sued for exposure to asbestos from their mines or products. They were not compensated for work on this paper and the lawyers for the injured plaintiffs did not review this paper and had no input into the content of the article.

Disclaimer: Historic testing of talc for asbestos is limited in methodology and scope. Courts and plaintiff lawyers have agreed, without the knowledge or permission of their clients, to keep secret some of the documents reported here; these documents became public during court proceedings over the objections of J&J and Imerys. Many documents remain sealed.

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Clinical significance: We provide evidence that asbestiform minerals present in “cosmetic” talc causes ovarian cancer. We provide an estimate of asbestiform minerals inhaled per talc application and cumulative lifetime exposure. The unique combination of asbestiform minerals detected in cancerous tissue and “cosmetic” talc is a fingerprint for exposure to asbestos-containing talc.

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consumer talc contains asbestos and a review of the world's largest talc producers records indicated that talc mines contained asbestos, that asbestos cannot be removed from talc, and that talc used in cosmetics was not asbestos-free.^{41,74–82} Case control and cohort studies of talc use and ovarian cancer have not differentiated inhalation and perineal talc exposures, and have not considered inhalation exposures in their analyses; this has contributed to misclassification of exposed cases and inaccurate dose-response assessments.⁴² In addition, industry marketing studies from the 1970s indicate that up to 85% of women used talc powders thus many "controls" were probably exposed to asbestos containing talcs.^{42,83}

We report 10 cases of serous ovarian cancer among users of asbestos-containing Johnson & Johnson (J&J) cosmetic talc products. Unlike most previous studies on talc and ovarian cancer, we focused on inhalation exposures to asbestos during various talc uses and not perineal exposure.^{4,6,12,40} We measured inhalation exposures during perineal application of asbestos-containing cosmetic talc. Based on exposure histories, we estimate the dose of inhaled asbestos and the increase in ovarian cancer risk for each case. Our case series also includes tissue analysis for talc and asbestos in both product and cancer tissue. By synthesizing current knowledge of asbestos carcinogenicity and evidence of asbestos in consumer talc products, our case series provides novel insight into the link between cosmetic talc use and ovarian cancer.

MATERIALS AND METHODS

We report 10 cases of serous ovarian cancer in women who primarily or exclusively used a variety of J&J cosmetic talc products including Johnson's Baby Powder (JBP), Shower to Shower (STS), and STS Shimmer.⁸⁴ These cases were identified among a group of 22 plaintiffs in Ingham et al versus Johnson & Johnson et al. All plaintiffs were diagnosed with ovarian cancer after exposure to J&J cosmetic talc products and transmission electron microscope (TEM) tissue analysis for talc and asbestos was performed for 10 of these plaintiffs. We only report on the 10 plaintiffs for whom TEM tissue analysis was completed.

There was no requirement for ethics review or institutional review board approval because this research was not experimental and patients participated voluntarily in conjunction with a lawsuit. Informed consent for publication was obtained from all living patients. One patient (Case No. 8) passed away after her exposure history was collected but before consent for publication was obtained. In this case, consent was obtained from the surviving spouse. For the remaining two deceased patients (Case No. 4 and Case No. 9), authors relied only on public information revealed during court proceedings. For the exposure assessment, the researcher wore a respirator and was decontaminated post-assessment. The researcher was not exposed to any risk, required to reveal personal information or subjected to specimen collection. The assessment did not meet the requirements to necessitate Institutional Review Board (IRB) approval.⁸⁵

Patient Histories

Medical histories, exposure histories (history questionnaire attached as Appendix 1, <http://links.lww.com/JOM/A685>), and physical examinations were collected for all living patients (8/10 cases). Exposure histories included questions about talc powder use and other sources of asbestos exposure. We analyzed the frequency and duration of talc uses for each case. For the two deceased patients (Case No. 4 and Case No. 9), a rough exposure history was compiled from the testimony of relatives who were familiar with each patient. Available medical records were also reviewed for all cases.

Exposure Assessment—Perineal Application

The exposure assessment was completed in a 15" × 15" × 8" room with appropriate negative asbestos airflow technology. The

experiment was videotaped using two Sony Model HDR-CX900 cameras with alternating Tyndall and standard lighting. (See Appendix 2, <http://links.lww.com/JOM/A686>.) Area and background samples were collected using four high-volume area sampling pump stations set up 5" to 6" from the talc user; these pump stations used 25 mm air cassettes containing 0.8 µm pore size mixed cellulose ester (MCE) filters with 5.0 µm backing pads and were calibrated to run at 10 L/min. Personal samples were collected using four low-volume pumps affixed to the talc user with the cassettes adjusted to be in the breathing zone of the investigator; the "personal" pumps were calibrated to 2.5 L/min. During the experiment, air samples were collected for 5 minutes from all sources.

A researcher wearing personal protective equipment and "personal" air pumps used a metal container of JBP for the experiment. Based on JBP advertisements featuring product images, we estimated that the JBP used in this test had been manufactured sometime in the 1950s and sourced from the Val Chisone mine.^{86,87} (See Appendix 3, <http://links.lww.com/JOM/A688> for images of JBP product tested and for full written report on exposure assessment.) J&J used this mine source from 1946 until 1968 and 1980 to 1981.^{86–88} From 1969 to 2003, J&J used Vermont talc in their powder products and later switched to Chinese talc.^{42,89} Using *t* test analysis, the asbestos content (fibers per gram) in all the bottles tested were statistically comparable across these three talc sources. (See Appendix 4, <http://links.lww.com/JOM/A689>)

The JBP can was weighed before the experiment using a Fisher Scientific balance. The researcher wore a bikini bottom over an inner pair of boxer briefs and sat on a chair in the middle of the room for the experiment. To simulate perineal talc application, the researcher shook the talc powder into his hand twice and then rubbed the powder into the upper leg area. This was repeated for the other leg. Then, the researcher stood, pulled the bikini bottom down and away from the body, and applied two squeezes of talc powder into the bikini bottom. The researcher released the briefs and sat down on the chair for the remainder of the study. The metal container of JBP was weighed again following the study. After the study, two field blanks were opened inside the study room.

A total of four background samples, four personal samples, and four area samples were collected along with two field blanks. All 12 air samples were analyzed for asbestos by the National Institute Occupational Safety and Health (NIOSH) 7400 phase contrast microscopy method using "A" counting rules and by the NIOSH 7402 TEM method.^{90,91} For TEM analysis, amphibole asbestos fibers or bundles with substantially parallel sides and an aspect ratio of 3:1 or greater, at least longer than 5.0 µm in length and greater than 0.25 µm were counted as per NIOSH 7402 asbestos structure sizing rules.⁹¹ The four personal air samples were also analyzed by the NIOSH 7402 method for fibrous talc particles.⁹¹ The two field blanks were analyzed for asbestos by phase contrast microscopy and TEM in accordance with NIOSH 7400 and NIOSH 7402.^{90,91}

Dose Calculations

For each case, we calculated asbestos dose in environmental fiber years (for consistency with the Environmental Protection Agency (EPA) risk assessment model) and in total fibers inhaled (to account for changes in respiratory intake in infancy vs. adulthood).⁹² We used the asbestos dose in environmental fiber years to calculate the excess risk. (See section on Dose–Response Risk Assessment.)

We calculated total asbestos dose based on the four most common usages of J&J talc powder reported among the 10 cases: perineal application (10/10), upper body powdering (9/10), exposure as an adult during diapering (8/10), and exposures as an infant during diapering (7/10). For each of these scenarios, we incorporated the intensity of the exposure (f/cc), duration of each exposure (minutes), and total number of applications (from exposure

histories) to calculate the dose. Although we did not adjust for latency, we excluded exposures that occurred after ovarian cancer diagnosis. Fibrous talc exposures from powdering were excluded from our calculations except exposure from baby diapering.⁴¹ Dement et al⁹³ did not differentiate type of fiber detected.

For perineal powdering exposures, we relied on measurements from our exposure assessment. (See above.) Air samples were collected over the course of 5 minutes in this test.

For upper body powdering, we used Gordon's et al⁴¹ measurements for shaker application of cosmetic talc powder to the underarm, shoulder, and upper arm area. Gordon et al⁴¹ used Cashmere Bouquet, which used the same Italian mine source as J&J (Val Chisone) from 1940 until 1992.^{94,95} Gordon et al⁴¹ found that users were exposed to 1.9 f/cc of asbestos fibers over the course of 5 minutes.⁴¹

For exposures during diapering, Dement et al⁹³ from NIOSH found that an adult is exposed to 2.2 f/cc of fibrous material and that a baby is exposed to 1.8 f/cc over the course of two minutes. When subjects reported that their parents had used talc on them during diaper changes as an infant, we relied on diaper changing norms to estimate infant exposures. United States market research and survey data show that diaper changes typically occur 8 to 10 times per day for infants (0 to 6 months) and 4 to 6 times per day for toddlers (6 to 24 months).^{96–98} Diaper changing frequency in the U.S. also changed over time: the average number of diaper changes per day over the first two years of life dropped from eight times per day in the 1960s to 5 to 6 times per day by the 1980s due to improvements in disposable diapers and reduction in cloth diaper use.^{97,99} Since all of the women in our series were born prior to 1975, we assumed that diaper changes occurred eight times per day for two years.

We calculated the dose for each case in fiber years ($\frac{f}{cc} \times year$) using the same conversions as Anderson et al.¹⁰⁰ For consistency with the EPA dose-response curve used for our risk assessment, we calculated the total duration of exposure based on a continuous, 24-hour exposure period (525,600 min/yr) until date of diagnosis.⁹²

Formula 1:

Formula to estimate inhalation exposure from talc application:

$$\text{Asbestos exposure in } \frac{f}{cc} \times \frac{\text{duration of each exposure} \times \text{total number of applications}}{525,600 \text{ min per year}} = \text{total dose in } \frac{f}{cc} \cdot \text{years}$$

We also calculated the total number of asbestos fibers inhaled in each case. For adults, we used the National Research Council (NRC)'s estimate of "an annual inhaled air volume of 7,300 m³" and formula to convert the dose from fiber years to total fibers.¹⁰¹ We relied on measurements of infant lung volume from Hall¹⁰² and on median infant respiratory rates calculated by Fleming et al¹⁰³ to estimate the total inhaled air volume for infants from age 0 to 2. Using time-weighted averages for tidal volume and respiratory rate, we calculated that infants breathed 11,025,072,000 ccs in the first 2 years of life, or 5,512,536,000 ccs per year on average.

Formula 2:

Formula to convert adult exposures to total fibers based on NRC (1984):

$$\left[\text{total does in } \frac{f}{cc} \times \text{years} \right] \times \frac{7,300,000,000 \text{ cc}}{\text{year}} = \text{Total number of asbestos fibers}$$

Formula 3:

Formula to convert infant exposures to total fibers based on Hall¹⁰² and Fleming et al¹⁰³:

$$\left[\text{total does in } \frac{f}{cc} \times \text{years} \right] \times \frac{5,512,536,000 \text{ cc}}{\text{year}} = \text{Total number of asbestos fibers}$$

We added together adult and infant exposures to calculate the exposures in total number of asbestos fibers. See Appendix 5, <http://links.lww.com/JOM/A690> for the full dose calculations for each case.

Dose–Response Risk Assessment

We developed a method to apply the EPA dose–response curves for inhaled asbestos and mesothelioma risk to ovarian cancer risk.⁹² First, we examined the EPA dose–response table for mesothelioma from environmental asbestos exposure (24-hours, 365 days per year).⁹² Utilizing the EPA dose–response estimates, we extrapolated a formula for the line of best fit for mesothelioma risk.

We then identified studies that reported mesothelioma and ovarian cancer rates in the same cohort and calculated comparative risk of mesothelioma versus ovarian cancer for each study.^{58,62,63,68,71} (See Table 1.)

Using these studies, we calculated the geometric mean comparative risk of contracting mesothelioma versus ovarian cancer from the same asbestos exposures. We applied this comparative risk to the line of best fit for mesothelioma based on the EPA dose–response data to determine a formula for risk of ovarian cancer.

The subjects of the EPA occupational exposure study were entirely men.⁹² Since women are more susceptible to cancer from asbestos exposure, we used Lacourt's¹⁰⁴ findings comparing the mesothelioma odds ratio (OR) in men versus women with the same exposures to adjust the formula for the increase in cancer risk for women. At total doses more than 0 to 0.1 fiber years, women were 1.725 times more likely to have mesothelioma than men.¹⁰⁴ At total doses more than 0.1 to 1 fiber years, women were 2.855 times more likely to have mesothelioma than men.¹⁰⁴ We applied these ratios to the EPA dose curve calculated to obtain a better estimate of the ovarian cancer dose–response in women.

The resulting dose–response curve for inhaled asbestos and ovarian cancer is shown in Fig. 1. We used each case's asbestos dose estimate in fiber years to identify their relative lifetime risk of developing ovarian cancer along the dose–response curve. We then compared each case's risk of contracting ovarian cancer due to inhaled asbestos exposure to the expected incidence of ovarian cancer for those without asbestos exposure: 11.4 per 100,000 from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) Program.¹⁰⁵

Tissue Analysis for Asbestos and Talc

Samples from a combination of the left and right ovaries, left and right fallopian tubes, and left and right pelvic lymph nodes were obtained from the hospital for each of the 10 patients. Tissues were analyzed to identify and quantify talc and asbestos content in the tissue.

For tissue analysis, a small portion of the tissue in each block was removed with a clean razor blade and placed in a pre-weighed 20 to 30 mL borosilicate glass vial. The vial was filled with 10 mL of filtered extraction solvent (hexane) and placed in a 60 °C water bath. The filtered extraction solvent was replaced every 20 minutes for a total of three changes. After the last extraction solvent change, two changes of filtered ethanol (10 mL, each) 10 minutes each were performed, then the tissue piece(s) were dried at 110 to 120 °C.

TABLE 1. Studies with Both Mesothelioma and Ovarian Cancer Rates in the Same Cohort and Calculated Comparative Risk of Mesothelioma to Ovarian Cancer in Female-Only Cohorts

Study	Mesothelioma Risk (SMR)	Ovarian Cancer Risk (SMR)	Comparative Risk M/OC
Loomis 2009	10.92	1.23	8.88
Magnani 2008	51.49	2.27	22.68
Pira 2016	51.3	3.03	16.93
Wang 2013	166.67	7.69	21.67
Wilczyńska 2005	22.67	1.76	12.88
Geometric mean of comparative risk			15.69

Tissue samples were digested with 15 to 30 mL of filtered sodium hypochlorite (appx. 8.0% bleach). After digestion, the remaining digested material was filtered through a 25 mm, 0.4 μm polycarbonate (PC) filter. The filter containing the tissue residue was dried and subsequently prepared for TEM examination.

A paraffin control sample (wax blank) was obtained by dissolving a known quantity of the paraffin blocks (devoid of tissue) in 10 mL of filtered extraction solvent and the dissolved solvent/wax solution was then filtered onto a 25 mm, 0.4 μm PC filter. The filter was allowed to dry and then prepared for TEM analysis. A process blank (sample vial) was prepared in the same manner and followed the wax blank and tissue sample vials through all steps.

For TEM analysis, 100 to 300 grid openings were analyzed for all asbestos and talc structures at a magnification of between 4000 and 20,000 \times . As per standard TEM analysis protocols, asbestos fiber/bundle identification was done by morphology (substantially parallel sides and length to width ratio of at least 5:1), length (greater than 0.5 μm in length), selected area electron diffraction (SAED), and energy dispersive X-ray spectroscopy (EDS).^{106–112} Talc structures (platy and fibrous) were identified morphologically, by selected area diffraction (SAED), and energy dispersive spectroscopy (EDS).

RESULTS

Exposure Assessment

Total weight used during the application process was 4.05 g of talc powder. For the five minute sampling time, the average total fiber exposure was 4.52 f/cc (5.86, 4.38, 3.85, and 3.98 f/cc), the average asbestos exposure was 2.57 f/cc (4.51, 1.88, 2.07, and 1.81 f/cc), and the average talc exposure was 1.95 f/cc (1.35, 2.50, 1.78, and 2.16 f/

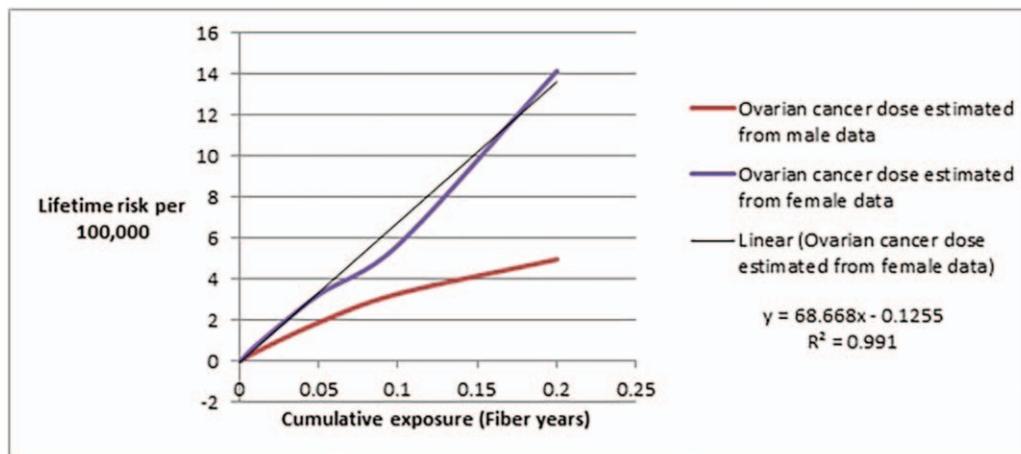
cc) for the talc user personal samples. For area samples, the average total fiber exposure was 0.41 f/cc (0.52, 0.28, 0.42, 0.40 f/cc), the average asbestos exposure was 0.2 f/cc (0.31, 0.20, 0.13, and 0.16 f/cc) and the average fibrous talc exposure was 0.19 f/cc (0.13, 0.08, 0.29, and 0.24 f/cc). The type of asbestos fiber identified in all samples was tremolite asbestos. No fibers were detected in the background samples or field blanks. The complete exposure assessment report, including count sheets and fiber images, is available as Appendix 3, <http://links.lww.com/JOM/A688>.

Dose Calculations and Risk Assessment

Results for dose calculations, risk assessment, and tissue analysis are summarized in Table 2. See Appendix 5, <http://links.lww.com/JOM/A690> for complete past medical history, history of present illness, other ovarian risk factors, exposure history, and dose calculations for each case.

STS was comprised of talcum powder mixed with cornstarch. The STS products contained between 80% and 100% talc sourced from the same mines as JPB.⁸⁴ Only four cases used these products for brief or unknown periods of time. Case No. 3 reported infrequent use of unidentified facial make-up powder, and Case No. 6 reported infrequent use of generic store-brand talcum powder. We could not calculate exposures for the brief use of these unknown products.

All cases had pathologically confirmed serous ovarian cancer. Age at diagnosis ranged from 41 to 78 years, with a mean age at diagnosis of 51.1 years and median age at diagnosis of 50 years. By contrast, the median age of ovarian cancer diagnosis in the United States is 63 with most cases occurring in women aged 55 to 64. Seven of 10 cases tested negative for BRCA mutations; two cases were never tested (No. 2 and No. 5), and one case (No. 8) tested positive for BRCA2 variant L771 V.

**FIGURE 1.** Ovarian cancer dose response (adjusted for difference in female mesothelioma risk).

All cases reported perineal talc application; the frequency of perineal powdering with talc ranged from once per day to 10 times per day and the duration ranged from 24 years to 47 years. Nine of 10 cases reported upper body powdering with talc ranging from 1 to 5 times per day and lasting from 20 to 47 years. Seven of 10 cases reported that their parents used talc powder on them during diaper changes and eight of 10 cases used talc powder during diapering. The total asbestos dose from talc powder use ranged from 2,774,000,000 to 37,742,501,440 asbestos fibers (0.38 to 5.18 fiber years) and the average dose was 9,308,551,008 asbestos fibers (1.28 fiber years). No other known asbestos exposure was identified for any of the cases. Based on EPA dose-response estimates, the risk of developing ovarian cancer due to inhaled asbestos exposure was calculated to be 2.3 to 31.1 times greater in these cases compared with baseline risk for ovarian cancer.¹⁰⁵ On average, the risk of ovarian cancer increased 7.7-fold among these cases.

Tissue Analysis

Talc and/or asbestos was identified in the tissue from all cases. Platy talc was found in 9/10 cases (90%) with an average concentration of 264,487 structures per gram (s/g) (range, 0 to 2,057,640 s/g). Fibrous talc was found in 8/10 cases (80%) with an average concentration of 5878 s/g (range, 0 to 21,545 s/g). Tremolite asbestos was found in 6/10 cases (60%) with an average concentration of 6488 s/g (range, 0 to 22,000 s/g). Anthophyllite asbestos was found in 4/10 cases (40%) with an average concentration of 2393 s/g (range: 0 to 12,000 s/g). Ferro-anthophyllite asbestos was also identified in two cases (20%), winchite and richterite asbestos were identified in one case (10%), and crocidolite asbestos was identified in one case (10%). Two tremolite structures with aspect ratios less than 5:1 were observed in one case, but were not counted as asbestos.

In the “possible fallopian tube B” tissue of Case No. 2, a cluster measuring 20.0 × 16.0 µm was identified composed of 36 counted talc plates, two fibrous talc structures, and one tremolite fiber. (See Fig. 2.)

DISCUSSION

This case series identified asbestos and/or talc in the tissue of 10 women diagnosed with serous ovarian cancer and exposed to J&J cosmetic talc products. Prior to their ovarian cancer diagnosis, these women were exposed to as much as 2,774,000,000 to 37,742,501,440 asbestos fibers (0.38 to 5.18 fiber years) due to their use of J&J cosmetic talc products. In all reported cases, asbestos exposures due to J&J talc use resulted in a substantial increase in ovarian cancer risk (2.3 to 31.1) based on our model. Early median age of diagnosis (50 in this case series vs. 63 nationally), and the EPA dose response table, indicates that asbestos exposure in infancy may cause ovarian cancer to occur sooner than it would have occurred absent this exposure.^{92,105}

The asbestos type found in the perineal talc use inhalation exposure assessment (tremolite asbestos) and the predominant asbestos types identified in these tissue samples (tremolite and anthophyllite asbestos) matched the fiber types previously identified in cosmetic talc products and in talc mines.^{41,74,75,77–81} (See Table 3.) Researchers have previously identified anthophyllite asbestos in Johnson’s Baby Powder (by TEM analysis),⁷⁹ amphibole needles and fibers in baby powder sourced from Vermont,^{76,77} and tremolite asbestos fibers in commercial talc produced prior to 1975 from J&J’s talc source in Val Chisone, Italy.^{81,89}

In 2017, a bundle of tremolite asbestos fibers was found in a bottle of JBP purchased by Case No. 3 in 2014. (See Appendix 6, <http://links.lww.com/JOM/A691> for full purchase report.) Tremolite asbestos was also identified in Case No. 3’s right pelvic lymph node. (See Fig. 3.) Winchite and richterite asbestos were found in the tissue in one case. However, richterite was called sodium

tremolite prior to 1978.¹¹³ Winchite is found in talc from the Allamoore, Texas mine, and may have contaminated J&J Italian talc processed at the same plant in the 1970s.^{114–118} Similarly, Transite pipes present in Royston Plant for J&J baby products may have contaminated J&J talc with crocidolite.^{119,120} Furthermore, Colgate acknowledges that there is crocidolite in some talc.¹²¹

The most common structures identified by tissue analysis (platy talc, fibrous talc, tremolite and anthophyllite asbestos) strongly indicate talc powder as the source of asbestos exposure in these cases. Tremolite asbestos has had minor commercial production in India and Italy and is mainly found as an accessory mineral in talc, vermiculite, and chrysotile.^{122–124} Anthophyllite asbestos, which occurs as an accessory mineral in talc and chrysotile, has also had limited commercial use.^{123–125} Anthophyllite and tremolite together account for less than 1% of asbestos production and consumption worldwide.¹²⁴

None of the cases reported in this series had any known history of alternative asbestos or vermiculite exposure and no chrysotile or vermiculite was found in any of the tissue samples. Churg and Warnock¹²⁶ performed a population study of lung asbestos and noted that “... in women a major source [of asbestos fibers] may be cosmetic talc, which is often contaminated with anthophyllite and tremolite.” Finkelstein’s¹²⁷ analysis of mesothelial tissue found a statistically significant association for tremolite detected with talc in tissue. This association was higher for women, 82% of whom had talc in their tissue compared with 68% of men.¹²⁷ The increased use of talcum-based cosmetics by women, and the similar fiber type combination is a fingerprint of cosmetic talc migrating to the pelvic organs. The combination of talc with tremolite and/or anthophyllite asbestos, as identified by Finkelstein¹²⁷ and the 10 cases reported here, are a fingerprint for exposure to asbestos-containing talc.^{128–130} (Appendix 7, <http://links.lww.com/JOM/A692>: a chart of fibers detected in J&J compared with fibers in tissue). These results indicate that perineal use can result in important inhalation exposure to asbestos, which is an accepted route of transmigration to the peritoneum and ovary.¹³¹

Our exposure assessment found that cosmetic talc users can be exposed to 2.57 f/cc asbestos in the breathing zone during perineal talc application; this finding was generally in agreement with previous studies of asbestos exposures during talc use.^{41,93} The bottle of JBP used in this exposure assessment was tested by TEM which detected 15 million fibers per gram. Further analysis found asbestos in 56/90 JBP bottles with a range of 4400 to 15,100,000 asbestos fibers per gram (appendix 4, <http://links.lww.com/JOM/A689>). For comparison, Gordon et al⁴¹ conducted examination on 50 samples of a single brand of cosmetic talc, sourced from either Montana, North Carolina or Val Chisone. Gordon et al⁴¹ found a range of 1840 to 200 million asbestos fibers per gram. Asbestos is not evenly distributed in talc ores and sampling cannot be completely representative of exposure.^{88,132}

Gordon et al⁴¹ selected a bottle with 18 million asbestos fibers per gram for the inhalation study. The results for Gordon’s et al.’s⁴¹ simulation of body powdering, 1.9 f/cc, is comparable to our findings of 2.57 f/cc asbestos exposure per application. Application of cosmetic talc varies greatly, including differences in product, application time, grams per use, and location of application. In addition, talc is mined and milled prior to sale, potentially modifying fiber size or dispersing asbestos unequally in finished cosmetic talc product.¹³³ Talc was sourced from various mines and processing methods changed over time, adding to the variability of asbestos content in talc-containing cosmetic products. However, our findings of an asbestos fingerprint in the tissue reveal that regardless of the dose, exposure to talc-containing cosmetic products is sufficient to cause ovarian cancer.

We relied on NIOSH measurements by Dement et al⁹³ to calculate exposures during diapering, however these measurements did not account for airborne asbestos exposures that continued after

TABLE 2. Summary of Cases

Case Number	Diagnosis	Talc Exposure History						Pathological Examination		
		Age at Diagnosis	Perineal Powdering	Upper body Powdering	Infant Exposure During Diapering	Adult Exposure During Diapering	Calculated Asbestos Dose	Relative Increase in Ovarian Cancer Risk	Tissue Examined	Findings (Structures Per Gram of Tissue)
1	Metastatic high grade papillary serous carcinoma	45	10x/d, 40yrs	5x/d, 40yrs	8x/d, 2yrs	10x/d, 8yrs	37,742,501,440 fibers, (5.18 fiber years)	31.1	Ovary (R)	Platy talc (323 s/g), Fibrous talc (4,000 s/g), Fero-anthophyllite (3,667 s/g)
2	Poorly differentiated high grade serous ovarian carcinoma	53	1x/d, 36yrs	1x/d, 23yrs	8x/d, 2yrs	7.5x/d, 7.5yrs	4,892,501,440 fibers, (0.68 fiber years)	4.1	Ovary A	Fibrous talc (1,200 s/g), fero-anthophyllite (399 s/g)
3	High grade serous carcinoma	49	3x/d, 39yrs	3x/d, 20yrs	8x/d, 2yrs	7x/d, 5yrs	11,535,501,440 fibers, (1.59 fiber years)	9.6	Ovary, fallopian tube (R)	Platy talc (NSD)*
4	Poorly differentiated serous adenocarcinoma	78	1x/day, 43yrs [§]	unknown [§]	unknown [§]	unknown [§]	2,774,000,000 fibers, (0.38 fiber years)	2.3	Ovary (L)	Possible fallopian tube A Possible fallopian tube B
5	Low grade serous carcinoma	52	1x/d, 47yrs	1x/d, 47yrs	8x/d, 2yrs	10x/d, 10yrs	7,812,501,440 fibers, (1.08 fiber years)	6.5	Ovary (R)	Fibrous talc (8,202 s/g), Tremolite (2,001,503 s/g), Platy talc (13,343 s/g) [†]
									Int. Iliac lymph node (R)	Platy talc (12,308 s/g), Fibrous talc (4,720 s/g), Tremolite (22,000 s/g)
									Comm. Iliac lymph node (R)	Platy talc (5,000 s/g), Tremolite (5,000 s/g), Fibrous talc (7,720 s/g), Anthophyllite (3,860 s/g)
										Platy talc (50,600 s/g) (continues)

TABLE 2. (Continued)

Case Number	Diagnosis	Talc Exposure History						Pathological Examination		
		Age at Diagnosis	Perineal Powdering	Upper body Powdering	Infant Exposure During Diapering	Adult Exposure During Diapering	Calculated Asbestos Dose	Relative Increase in Ovarian Cancer Risk	Tissue Examined	Findings (Structures Per Gram of Tissue)
6	High grade serous papillary carcinoma	51	1x/d, 40yrs	1x/d, 40yrs	8x/d, 2yrs	10x/d, 10yrs	7,009,501,440 fibers, (0.97 fiber years)	5.8	Adnexa, tumor/ovary (R)	Platy talc (21,300/s/g)
7	Serous adenocarcinoma	56	1x/d, 37yrs	1x/d, 37yrs	Unknown	7.5x/d, 6yrs	5,183,000,000 fibers, (0.71 fiber years)	4.3	Adnexa, fallopian tube (L) Adnexa, fallopian tube (R)	Platy talc (4,720/s/g), Platy talc (12,000/s/g), Tremolite (12,000/s/g), Anthophyllite (12,000/s/g), Fibrous talc (1,090/s/g)
8	High grade ovarian serous carcinoma	44	1x/d, 24yrs	1x/d, 24yrs	Unknown	3.5x/d, 4yrs	2,993,000,000 fibers, (0.41 fiber years)	2.5	Ovary (L) Fallopian tube (R) Fallopian tube (L) Ovary (R)	Platy talc (10,500/s/g), Platy talc (8,500/s/g), Platy talc (10,900/s/g), Platy talc (3,340/s/g), Ferro-anthophyllite (1,670/s/g), Crocidolite (1,670/s/g)
9	Poorly differentiated serous papillary adenocarcinoma	41	1x/d, 42yrs [§]	1x/d, 42yrs [§]	8x/d, 2yrs [§]	n/a [§]	4,965,501,440 fibers, (0.69 fiber years)	4.1	Ovary (L) Fallopian tube (R)	Platy talc (7,400/s/g), Tremolite (1,380/s/g), Anthophyllite (1,385/s/g), Fibrous talc (9,690/s/g)
10	High-grade ovarian papillary serous carcinoma	42	2x/d, 32yrs	2x/d, 32yrs	8x/d, 2yrs	8x/d, 4yrs	8,177,501,440 fibers, (1.13 fiber years)	6.8	Ovary (L) Fallopian tube (L) Fallopian tube (R) Pelvic Lymph Node (L) Ovary, fallopian tube (R)	NSD [*] NSD [*] NSD [*] Fibrous talc (8,770/s/g) Platy talc (10,800/s/g)

^{*}No asbestos or talc structures detected.[†]Tissue received, but not analyzed.[‡]Richerite asbestos were known as sodium tremolite.[§]Patient deceased; exposure history based on recollections of family and friends.^{||}The final pathology report also noted minor components of transitional cell and mucinous carcinoma.[¶]Two tremolite structures were reported with an aspect ratio of less than 5:1 that were not counted.

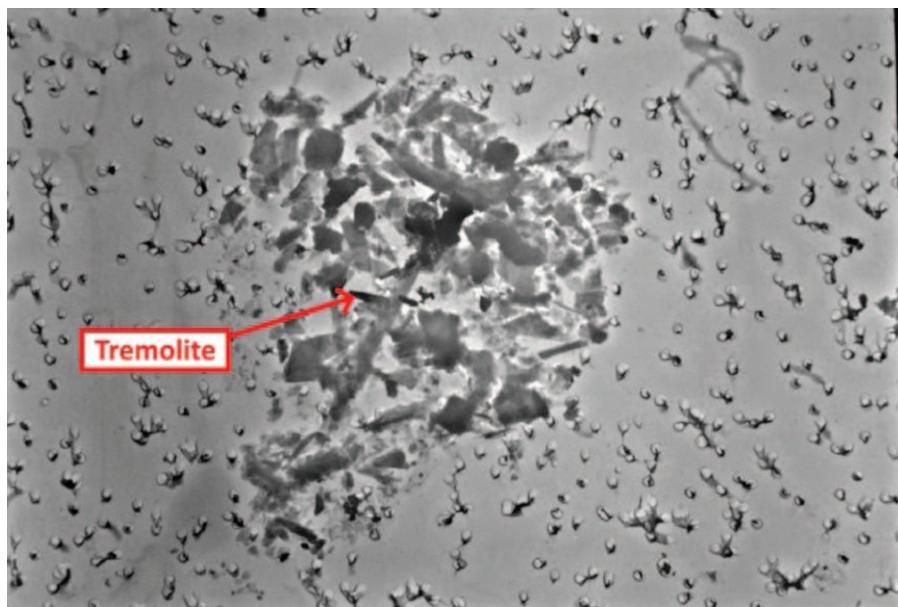


FIGURE 2. TEM image of cluster measuring $20.0 \times 16.0 \mu\text{m}$ composed of 36 counted talc plates, two fibrous talc structures, and one tremolite fiber identified in “possible fallopian tube B” tissue of Case No. 2.

the sampling time.⁹³ Dement et al⁹³ collected air samples for 2 minutes during a simulated diaper change with JBP, but another experiment in the same study indicated that exposures continued for at least 3 minutes and likely persisted for even longer. Dement et al⁹³ used phase contrast microscopy and did not differentiate between asbestos and fibrous talc. However, in 1968, NIOSH injected asbestos containing “cosmetic” talc into hamsters and detected tremolite asbestos bodies but no fibrous talc in the animal lungs.¹³⁴ Anderson et al¹⁰⁰ reported much lower levels during body dusting with talc (0 to 0.0039 f/cc). However, the microscopist in the Anderson et al^{100,135} study originally identified four anthophyllite asbestos fibers in the air samples by TEM, but changed the result to transition fibers at the request of the project supervisor due to concern that the results would be used in litigation.¹³⁵

Both our study and Gordon's et al⁴¹ exposures assessment used less talc powder than the average user: these experiments used 4.05 and 0.37 g of talc respectively, but J&J's unpublished studies found that women used 8.16 g and men used 13.02 g of talc powder on average during body powdering.^{41,136} Anderson et al¹⁰⁰ reported that subjects used 11.6 g of talc on average to powder their bodies after showering. Therefore, our use estimates were 3 to 20 times lower than Anderson et al¹⁰⁰ and J&J's.

We also excluded many reported talc uses from our dose calculations due to a lack of exposure data. For instance, three cases (No. 1, No. 3, and No. 5) regularly used talc powder on their sheets and pillows; several other cases also reported seeing and smelling dust in the air while cleaning the room where they regularly applied talc. (See Appendix 5, <http://links.lww.com/JOM/A690> for complete exposure

TABLE 3. Summary of Studies Reporting Asbestos in Consumer Talc Products

Study	Test Method	Summary of Findings
Rohl et al (1976)	XRD, PLM, TEM, SEM	0.1–14% tremolite and anthophyllite (mostly fibrous) by weight in 10 of 20 consumer talc products tested
Paoletti et al (1984)	TEM	0.5–1.6% tremolite asbestos in two of six Italian cosmetic talc powders tested Trace to 0.15% chrysotile in 3 of 14, 18.7–21.7% anthophyllite asbestos and tremolite asbestos in 2 of 14, and 0.13% tremolite asbestos & chrysotile in 2 of 10 samples provided by the European Pharmacopeia
Blount (1991)	PLM	10 to 341 structures per mg amphibole fibers, needles, cleavages and “prismatic pieces” in 9 of 14 samples of pharmaceutical and cosmetic-grade talc powders tested
Jehan (2004)	PLM	Qualitative identification of tremolite asbestos in 13 of 28, chrysotile in 12 of 28, anthophyllite asbestos in 3 of 28, and a mixture of asbestos fibers in 4 of 28 cosmetic talc powder products used in Pakistan
Floyd (2004)	TEM	0.20% anthophyllite asbestos by weight in Johnson's Baby Powder
Mattenkrott (2009)	SEM	0.001–0.0073% asbestos by weight in 13 of 57 samples of talc powders sold on the German market from 1996 to 2005
Gordon et al (2014)	PLM	1,840–1,104,000 fibers per gram asbestos in 50 of 50 historical samples of one brand of cosmetic talc powder tested (40 of 50 contained anthophyllite asbestos only, four contained tremolite asbestos only, four contained tremolite and anthophyllite asbestos, two contained tremolite, anthophyllite, and chrysotile asbestos)
	TEM	0.004–0.9% amphibole asbestos by weight in nine of nine samples of the same cosmetic talc product
Ilgren et al (2017)	TEM	3.687×10^6 tremolite asbestos fibers/g in an authentic sample of commercial talc produced prior to 1975 from the talc mine in Val Chisone, Italy

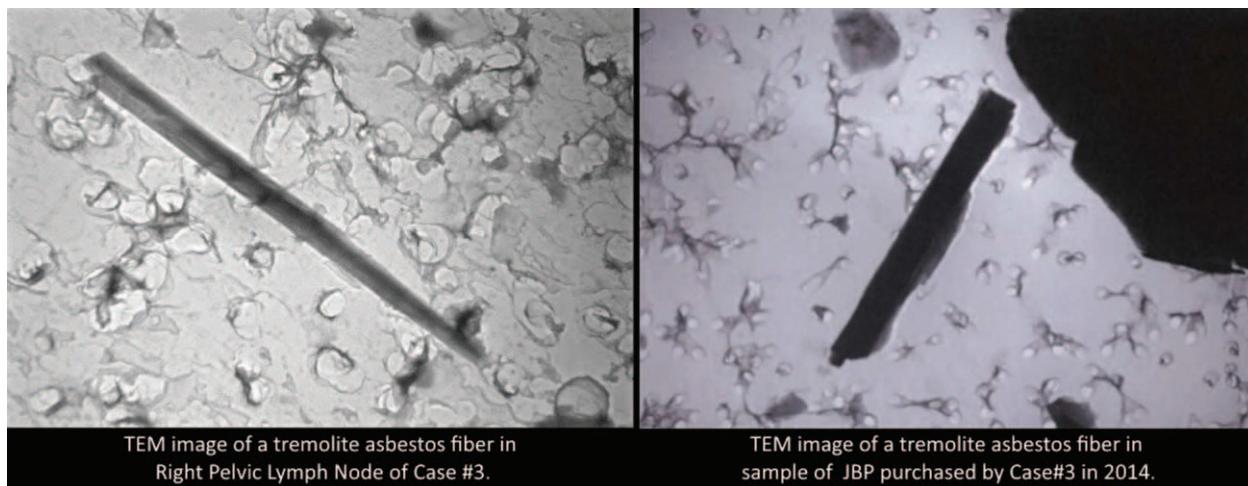


FIGURE 3. TEM images of a tremolite asbestos fibers in Case No. 3 right pelvic lymph node tissue (left) and in sample of JBP purchased by Case No. 3 in 2014 (right).

histories.) Although our findings indicate that asbestos is present in consumer talc products at a level sufficient to cause disease, our dose estimates may under or over estimate the total exposure to asbestos in talc in these cases.

Burns et al¹³⁷ created a dose estimation-model for cosmetic talc, relying on previous assessments to predict asbestos exposure, including Moon et al¹³⁸, Gordon et al⁴¹, Russell et al¹³⁶, and Anderson et. al.¹⁰⁰ Burns's et al¹³⁷ assessment was based on an assumption of 0.1% level of asbestos in talc mathematical model that incorrectly reduced the exposure estimate by 1000. For example, Gordon et al⁴¹ reported, 4.8 f/cc, however, Burns's et al¹³⁷ math model reduces this figure to 0.0048 f/cc. In comparison, Addison et al (1988)¹³⁹ reported that dusts containing 0.1% asbestos may release 1.17 to 2.79 asbestos fibers/cc into the air, consistent with our measurements.

Our tissue analysis results were consistent with previous reports of asbestos and/or talc in ovarian tissue.^{136,140–144} (See Table 4.) The number of asbestos structures per gram, however, was approximately one order of magnitude lower in our study than in previous quantitative studies of asbestos in ovarian tissue.¹⁴³ This discrepancy may be due to differences in tissue preparation and analytical procedures. Other quantitative studies relied on wet tissue weight for their analysis whereas we used a dry weight procedure.¹⁴³ Additionally, we counted 100 to 300 grid openings in our study while other studies appear to have counted the entire grid area.¹⁴³ We also found that some tissue samples contained “hot spots” with very high concentrations of asbestos and/or talc compared with the surrounding tissue. (See Fig. 2.) The occurrence or absence of “hot spots” may also account for variability in reported asbestos concentrations in tissue. The predominant types of asbestos identified in our series (tremolite and anthophyllite asbestos) are the same as those most commonly reported in past studies.^{140,143,144}

We did not consider latency in our risk estimate because our calculations followed the EPA risk assessment, which did not consider latency.⁹² In addition, Pira et al⁶⁸ found that for asbestos-caused ovarian cancer “...the SMRs increased monotonically with time since first employment, although the number of deaths was small in several categories...” Our omission of latency from this study is to remain consistent with the EPA assessment and reflect the lack of effect demonstrated by Pira's et al analysis.

We omitted fibrous talc from our risk assessment due to a lack of dose-response data in the published literature. IARC has previously classified fibrous talc as a Group 1 carcinogen and OSHA regulates fibrous talc per the asbestos standard.^{3,43,145–147} Further research on the relationship between talc powder use and ovarian cancer should include studies of fibrous talc toxicity.

CONCLUSION

Of the 10 reported cases of serous ovarian cancer, all were found to have talc and eight were found to have asbestos in their tissue samples. The main types of asbestos identified in tissue, tremolite and anthophyllite, constitute a fingerprint for talc containing asbestos and indicate that “cosmetic” talc powder as the source of asbestos exposure in these cases. IARC has concluded that asbestos is an ovarian carcinogen.⁴³ IARC has likewise classified talc containing asbestiform fibers (including both asbestos and fibrous talc) as a carcinogen.^{3,43,148} These cases provide more evidence of the causal link between asbestos, talc, and ovarian cancer and indicate that asbestos is present in consumer talc products at a level sufficient to cause disease.

In 1973, J&J told the Food and Drug Administration (FDA) that “Johnson & Johnson’s policy of full cooperation with FDA and that if the results of any scientific studies show any question of safety of talc, Johnson & Johnson will not hesitate to take it off the market” and their corporate position is that there is no known safe level of exposure to asbestos.¹⁴⁹ J&J’s studies have shown that asbestos has been present in its cosmetic talc ores since the 1950s. In 2019, the FDA has found asbestos in JBP sourced from China and Claire’s cosmetics.^{150,151} At least three retailers of cosmetic talc accept the causal relationship between talc use and ovarian cancer: Angel of Mine, Perfect Purity, and Assured Body and Foot Powders warn that “frequent application of talcum powder in the female genital area may increase the risk of ovarian cancer.”¹⁵² In addition, J&J’s talc supplier Rio Tinto Minerals has warned its customers since 2006 of this risk in Material Safety Data Sheets (MSDS) for talc: “perineal use of talc-based body powder is possibly carcinogenic to humans.”^{153,154} J&J removes this warning from its talc MSDS and cosmetic talc products.¹⁵⁵ Because talc powder is a cosmetic product with no medical benefit, these warnings still do not warrant the sale of a products when the benefits cannot outweigh the risks, especially when there is a safer substitute.^{156–158}

TABLE 4. Summary of Studies Finding Asbestos and/or Talc in Ovarian Tissue From Cosmetic Talc Use

Study	Tissue Weight Type	Test Method	Summary of Findings
Henderson et al (1971)	n/a	TEM	Qualitative identification of talc in 10/13 ovarian tumors Qualitative identification of talc in 12/21 cervical tumors
Langer (1971)	n/a	Unknown	Qualitative identification of talc and chrysotile asbestos in Henderson et al (1971) samples
Heller, Westhoff et al (1996)	Wet weight	PLM	26–464 talc particles per gram in 12/12 samples of benign ovarian neoplasms from 12 women with history of adult perineal talc use 69–420 talc particles per gram in 11/11 samples of benign ovarian neoplasms from 12 women with history of talc diapering during infancy 6–2,200 talc particles per gram in 6/7 samples of benign ovarian neoplasms from 12 women with no history of adult perineal talc use and an unknown history of other talc uses
		TEM	151,300–7,565,000 talc particles per gram in 5/12 samples of benign ovarian neoplasms from 12 women with history of adult perineal talc use 151,300–1,600,288 talc particles per gram in 6/11 samples of benign ovarian neoplasms from 12 women with history of talc diapering during infancy 63,042–1,669,000 talc particles per gram in 3/7 samples of benign ovarian neoplasms from 12 women with no history of adult perineal talc use and an unknown history of other talc uses
Cramer et al (2007)	n/a	PLM and SEM	Qualitative identification of birefringent particles consistent with talc in pelvic lymph nodes of a 68-year-old woman with stage III ovarian papillary serous carcinoma and a 30-year history of perineal talc use

J&J should comply with its self-proclaimed obligation to take talc-containing cosmetic products off the market “if the results of any scientific studies show any question of safety of talc, Johnson & Johnson will not hesitate to take it off the market.”¹⁴⁹

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